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July 24, 2006

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Application No.	:	**2,378,265**
Owner	:	DAINIPPON SUMITOMO PHARMA CO., LTD.
Title	:	**SOLID PREPARATIONS CONTAINING CHITOSAN POWDER AND PROCESS FOR PRODUCING THE SAME**
Classification	:	A61K 47/36 (2006.01)
Your File No.	:	**47434-NP.**
Examiner	:	Owen Terreau

YOU ARE HEREBY NOTIFIED OF A REQUISITION BY THE EXAMINER IN ACCORDANCE WITH SUBSECTION 30(2) OF THE *PATENT RULES*. IN ORDER TO AVOID ABANDONMENT UNDER PARAGRAPH 73(1)(A) OF THE *PATENT ACT*, A WRITTEN REPLY MUST BE RECEIVED WITHIN **6** MONTHS AFTER THE ABOVE DATE.

This application has been examined taking into account the:

Description,	pages 5-7, 9, 10, 1, 16, 18-21, 23-25, and 28, as originally filed; pages 1-4, 8, 11-14, 17, 22, 26, and 27, as received on 2004-01-14 during the national phase;
Claims,	7-9, as originally filed; 1-6, as received on 2004-01-14 during the national phase; and
Drawings,	pages 1/11 - 11/11, as originally filed.

This application has been examined taking into account applicant's correspondence on prior art received in this office on December 17, 2003.

The number of claims in this application is 9.

A search of the prior art has revealed the following:

Reference Applied:

Canadian Application

D1 2,305,762	1999-04-22	A61K 9/28	Lerner et al.

Lerner et al. disclose a gastrointestinal delivery system comprising a core and a coating. The coating comprises a water-insoluble material in which a particulate material is embedded.

The examiner has identified the following defects in the application:

The claims on file do not comply with paragraph 28.2(1)(*b*) of the *Patent Act*. D1 disclosed the claimed subject matter before the claim date. D1 discloses a gastrointestinal delivery system comprising a core containing a drug, said core being surrounded by a coating. The coating comprises a water-insoluble or relatively water-insoluble material in which a water-insoluble particulate is embedded (see D1 abstract, claim1, page 14, line 7 - page 15, line 9). The insoluble material includes Eudragit®-RS (ethyl acrylate-methyl acrylate-trimethylammoniumethyl methacrylate (page 27, lines 2-3) or ethyl cellulose (page 34, line 18 and Examples). Chitosan is disclosed as a possible water insoluble particulate (page 26, line 21). The coated tablet can be further coated by an enteric coating (page 25, line 29 - page 26 - 1). The product is made by spray coating the core with a solution of the polymer and particulate (page 17, lines 4-8).

Claim 6 is indefinite and does not comply with subsection 27(4) of the *Patent Act*. It is unclear how a solid medicament is coated with a solution. It is suggested that the process define a step of applying the solution to produce the coating, since the solution is not a coating, per se.

Claim 7 is broader in scope than the teaching of the description and does not comply with section 84 of the *Patent Rules*. The description states at page 1, lines 7-8 that "The present invention relates to a **colonic delivery** solid preparation". This should be incorporated in this claim. It also seems that a coating comprising an enteric polymer is required for the invention to achieve the promised result of colonic delivery.

In view of the foregoing defects, the applicant is requisitioned, under subsection 30(2) of the *Patent Rules*, to amend the application in order to comply with the *Patent Act* and the *Patent Rules* or to provide arguments as to why the application does comply.

Under section 34 of the *Patent Rules*, any amendment made in response to this requisition must be accompanied by a statement explaining the nature thereof, and how it corrects each of the above identified defects.

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